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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,220	BALWANI ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7-10,12-14 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *10,12-14 and 16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7-9 and 20-25* is/are rejected.

7)☒ Claim(s) *4,5,8, 9,21,22,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of May 6, 2008 made to the office action filed February 6, 2008. Claims 3-5, 7-10, 12-14 and 16-25 are pending. Claims 3-5, 7-10, 12-14, 16-18 are amended and claims 21-25 are new.

The Applicant's request for rejoinder has been considered but is not persuasive because as stated in the previous office action the method of use in composition claims do not receive patentable weight. Thus, the claimed composition can be used for asthma instead of to treat cough and nasal congestion. Additionally, while the searches of Group I and II may be overlapping, there is no reason to believe that the searches would be coextensive. In searching Group I, Examiner will be focusing on the patentability of the composition itself, and not the method of treating and relieving the distress of cough and nasal congestion of Group II. Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of treatment and not the composition itself. Therefore, the restriction is still deemed proper.

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive, thus the rejections are upheld: 1) the obviousness double patenting rejection of claims 1-9 as being unpatentable over claims 1-3 and 7-10 of U.S. Patent No. 6,462,094 B1 in view of

Venkataraman; 2) the 35 USC 103(a) rejection of claims 1-9 as being unpatentable over Venkataraman.

Due to the amendment to the claims, the modified and/or new obviousness double patenting, 35 USC 103(a) rejections, and claim objections are made below. The Applicant's arguments are addressed below.

Claim Objections

Claims 4, 5, 8, 9, 21, 22, 24 and 25 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The current independent claims have fixed ranges, then the dependent claims have the claim language "about". For instance in claims 3, there is 20 to 30 mg of phenylephrine tannate and in claim 4, there is about 25 mg of phenylephrine tannate, which reads to a range of 20 to 30 mg. Therefore, the dependent claims do not limit the independent claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-5, 7-9, 21 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 7-10 of U.S. Patent No. 6,462,094 B1 ('094) in view of Venkataraman (US 6,509,492 B1).

The US Patent '094 teaches a therapeutic composition for the symptomatic relief of cough comprising pharmaceutically effective amounts of active ingredients consisting of phenylephrine tannate and guifensin in tablet or suspension form (see claims 1-3). The amounts of phenylephrine tannate can be from about 20 to 30 mg, about 25 mg, about 3 to 8 mg, about 5 mg, and the amounts of guaifenesin can be from about 100 to 300 mg, about 200 mg, about 50 to 150 mg and about 100 mg, per 5 mL of suspension (see claims 7-10).

'094 does not teach pyrilamine tannate or its amounts. '094 also does not teach one or more suitable pharmaceutical carriers, binding agents, and/or disintegrating agents.

Venkataraman teaches a tannate composition comprising an antihistamine, an antitussive and an expectorant such as pyrilamine tannate, phenylephrine tannate and guaifenesin tannate to treat cough and cold symptoms (see abstract; columns 6 and 7, table 1; and column 10, line 9-10). The compositions are compounded in a conventional manner with physiologically acceptable carriers, binders, stabilizers, flavors or the like, as called for by accepted pharmaceutical practice (see column 2, lines 4-10).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of '094 and an expectorant such as pyrilamine tannate because it is known in the art to combine an expectorant with an antihistamine and an antitussive agent to treat coughs and colds. Also, one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of '094 and one or more suitable pharmaceutical carriers, binding agents, and/or disintegrating agents because Venkataraman teaches that these are conventional additions to these types of compositions (see column 2, lines 4-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 3-5, 7-9, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 6,509,492 B1).

Venkataraman teaches composition for treating upper respiratory indications, such as cough, cold, cold-like symptoms and symptoms related to upper respiratory infections comprising combinations of at least one or more agents into a single administrative dose (see abstract), such as the an antihistamine, an antitussive and an expectorant (see column 10, lines 9-10). Antihistamines include pyrilamine tannate; decongestants include phenylephrine tannate; and expectorants include guaifensin tannate (see columns 6 and 7, table 1; addresses claim 1). Suggested dosage amounts are not to be seen as limiting and are given in standard molecular compounds that would be converted to equivalent tannate compounds (see column 8, lines 36-40). Pyrilamine maleate is from 25-50 mg with a maximum daily dose of 200 mg; phenylephrine HCl has an oral dose of 10 mg and a maximum daily dose of 60 mg; and guaifenesin is from 200-400 mg with a maximum dose of 2400 mg (see columns 8 and

9, table 2; addresses claims 3-5 and 7-9). The composition can be in the form of a suspension or tablet (see column 2, lines 5-6; addresses claims 2 and 6), in which the suspensions are in 5 mL (see claims 1 and 2). The compositions are compounded in a conventional manner with physiologically acceptable carriers, binders, stabilizers, flavors or the like, as called for by accepted pharmaceutical practice (see column 2, lines 4-10). For instance, pectin can be used as an adhesive (see column 5, line 27), or glycerin can be used as an inert material (see column 19, lines 7and 8; addresses claims 21 and 22).

Venkataraman does not specifically teach the exact amounts of each compound as disclosed in claims 3-5, 7-9, 21 and 22.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Venkataraman and the amounts of each compound as disclosed in claims 3-5 and 7-9 because Venkataraman teaches a range that either overlaps or is close to the Applicant's amounts. In regards to the amounts of Venkataraman that are close the Applicant's amounts, the following teaching and note provides motivation and obviousness to the Applicant's amounts of each compound: 1) the suggested dosage amounts provided by Venkataraman are not to be seen as limiting (see column 8, lines 36-40); 2) maximum dosages for both adults and children are given by Venkataraman (see columns 8 and 9, table 2), which means

that the hourly dosage can be adjusted depending on the type of person being treated and as well as the hourly dosage is within the maximum dosage limit; and 3) it is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

2) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 6,509,492 B1) as applied to claims 3-5, 7-9, 21 and 22 above, in view of Gordziel (US 2001/0011104 A1).

The teachings of Venkataraman are as applied to claims 3-5, 7-9, 21 and 22 above.

Venkataraman does not teach the specific pharmaceutical carriers, binding agents, and/or disintegrating agents disclosed in claims 23-25 (i.e. pectin, kaolin, magnesium aluminum silicate, benzoic acid, methylparaben and glycerin).

Gordziel teaches an oral composition for relief of upper respiratory tract conditions comprising phenylephrine tannate, pectin, kaolin, magnesium aluminum silicate, benzoic acid, methylparaben and glycerin (see example 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Venkataraman and teach the specific pharmaceutical carriers, binding agents, and/or disintegrating agents disclosed in claims 23-25 (i.e. pectin, kaolin, magnesium aluminum silicate, benzoic acid, methylparaben and glycerin) because of the following teachings: Venkatarman teaches that the compositions are compounded in a conventional manner with physiologically acceptable carriers, binders, stabilizers, flavors or the like, as called for by accepted pharmaceutical practice (see column 2, lines 4-10); 2) Venkatarman also teaches that pectin can be used as an adhesive (see column 5, line 27), or glycerin can be used as an inert material (see column 19, lines 7and 8); 3) Venkatarman and Gordziel teach oral composition for treatment of cold symptoms comprising phenylephrine tannate; and 4) Gordziel teaches a suspension comprising phenylephrine tannate, pectin, kaolin, magnesium aluminum silicate, benzoic acid, methylparaben and glycerin (see example 2). Therefore, one of ordinary skill in the art would know conventional pharmaceutical carriers, binding agents, and/or disintegrating agents used in these types of compositions as taught by Gordziel.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that the ranges of the various active agents disclosed in Venkataraman are so broad that there could be no predicatability in selecting the amounts of active agents so as to render obvious the presently claimed invention. The term "about" in the claims does not provide any additional motivation or predictability to guide a person of ordinary skill in the art to select the ranges in the present claims from the broad ranges disclosed in Venkataraman. Venkataraman also fails to provide any guidance for choosing dosage amounts other than those specifically disclosed. Further only pyrilamine maleate/tannate and guaifenesin are indicated and neither in table 2 or 3 is phenylephrine tannate represented.

The Examiner disagrees because Venkataraman teaches that pyrilamine maleate/tannate is from 25-50 mg with a maximum daily dose of 200 mg (compared to Applicant's 40 to 80 mg or 25 to 35 mg); phenylephrine HCl/tannate has an oral dose of 10 mg and a maximum daily dose of 60 mg (compared to Applicant's 20 to 30 mg or 3 to 15 mg); and guaifenesin is from 200-400 mg with a maximum dose of 2400 mg (compared to Applicant's 100 to 400 mg or 50 to 300 mg; see columns 8 and 9, table 2). Thus, the ranges are not considered to be as broad as Applicant's state, because the ranges of Venkataraman overlap with the Applicant's ranges. The motivation to select the amount is to provide an effective composition to treat upper respiratory indications, such as cough, cold, cold-like symptoms and symptoms related to upper respiratory infections comprising combinations of at least one or more agents into a single

administrative dose (see abstract). Venkataraman also teaches that the suggested dosage amounts are not to be seen as limiting (see column 8, lines 36-40). Thus, it is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

In response to the "about" terminology, the amended claims have changed this argument to the current argument in the modified rejection.

In response to Venkataraman not showing an example with the applicant's composition, there is no statute that requires the prior art to demonstrate a specific example. The teachings of the prior art are taken as a whole. Also, the rejection presented by the Examiner is an obviousness rejection instead of an anticipated rejection. Venkataraman teaches composition for treating upper respiratory indications, such as cough, cold, cold-like symptoms and symptoms related to upper respiratory infections comprising combinations of at least one or more agents into a single administrative dose (see abstract), such as the an antihistamine, an antitussive and an

expectorant (see column 10, lines 9-10). Antihistamines include pyrilamine tannate; decongestants include phenylephrine tannate; and expectorants include guaifensin tannate (see columns 6 and 7, table 1). Thus, the Applicant's invention is obvious over the compositions of Venkataraman.

> The Applicant's claim impermissible hindsight was used by the Examiner in the obviousness rejection. The Applicant further submit that the courts have long held that the disclosure of a genus does not necessarily provide support for every species or subgenus within the genus.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The support for the species that the Applicant has selected has been taught by Venkataraman. Specifically, antihistamines include pyrilamine tannate; decongestants include phenylephrine tannate; and expectorants include guaifensin tannate (see columns 6 and 7, table 1).

> The Applicant argues the above arguments apply to the obviousness-type double patenting rejection.

The Examiner disagrees for the same reasons given above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617